

**REMARKS/ARGUMENTS**

Reconsideration of this application is requested. Claims 20-57 are in the case.

**I. CLAIM OBJECTIONS**

Claim 21 has been objected to as not beginning with the definite article "The" as opposed to the indefinite article "A". The dependent claims have been amended to meet this objection. No new matter is entered.

**II. THE 35 U.S.C. § 112, SECOND PARAGRAPH, REJECTION**

Claims 30, 32-45 and 50-57 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for the reasons detailed on page 3 of the Action. In response, and without conceding to the merit of the rejections, the claims have been amended to deal with the outstanding formal points. The following comments are offered.

Claim 30 has been rejected as allegedly indefinite because the claim recites a kit containing one of components (a) and (b) and instructions. Reconsideration of this rejection is requested. Claim 30 is an independent claim relating to a kit in which one of the two components (i.e. formulations) as defined in e.g. Claim 20 is supplied together with instructions to use that component with the other of the two components. The claim is intended to encompass a situation in which, for example, somebody supplies a low molecular weight thrombin inhibitor along with instructions to use that component in combination therapy with a prodrug of a low molecular weight thrombin inhibitor. Hence, the instructions would indicate that the second component should be included in

a method of co-administering with the first. The kit of parts of Claim 30 thus comprises two things, one of the components and instructions to use it along with the other. The claim is not unclear or indefinite. Withdrawal of this aspect of the formal rejection is respectfully requested.

Claims 32-44 and 54-57 stand rejected as allegedly indefinite as lacking an essential step in the method of treatment, namely the effective amounts of the pharmaceutical formulations administered. In response, the words "in an effective amount and" have been inserted before "for a time and" .

Claim 33 has been objected to as reciting the limitation "component (a)" and "component (b)" in lines 1 and 2. In response, "component" has been replaced by "formulation" wherever it occurs in Claim 33 and other claims.

Claims 45 and 50 stand rejected as allegedly indefinite because of the term "the thrombin inhibitor". The Examiner asks whether the thrombin inhibitor is the first or the second. In response, it is neither, it is just the thrombin inhibitor. Claim 45 is dependent on Claim 31, which claims a pharmaceutical formulation including a low molecular weight thrombin inhibitor and a prodrug of a low molecular weight thrombin inhibitor. Hence, the two components are an active thrombin inhibitor and a **prodrug** of a (i.e. any) thrombin inhibitor. In this respect, there is only one thrombin inhibitor in the formulation as such. Claim 45 merely recites that the prodrug is a prodrug of the same active thrombin inhibitor that is also part of the pharmaceutical formulation of that claim.

It is believed that outstanding 35 U.S.C. § 112, second paragraph, rejections should now be withdrawn. Such action is respectfully requested.

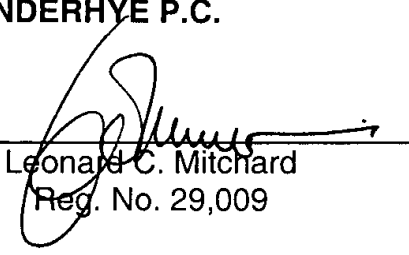
Allowance of the application is awaited.

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Respectfully submitted,

**NIXON & VANDERHYE P.C.**

By: \_\_\_\_\_

  
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